

Code	MAN-008-00
number	ALLERGEN CONTROL
Date of issue	May 13, 2018
Date modified	November 3, 2018
Objective	Check ingredients to prevent sources of allergens from contaminating the product.
responsible	Responsible for the Safety and Quality system.

1. GENERAL

Allergens are substances present in foods responsible for an immune reaction called *food allergy*.

2. MAIN ALLERGENS IN FOOD.

Top Allergens According to the "FDA Guidance Document for Food Researchers" These are eight foods considered "major food allergens" that cause 90% of allergic reactions to foods. P. And any ingredient sending proteins derived from one or more of them, the FDA enforces the Food Allergen Labeling and Consumer Protection Act, 2004 (FALCPA).

- Milk
- Egg
- Peanut
- Nuts
- Fish
- Seafood
- Soy
- Wheat

The nut category includes walnuts, almonds, pecans, hazelnuts, pistachios, cashew, pine nuts, macadamia nuts and Brazilian nuts. Seafood includes crab, crayfish, lobster, shrimp, clam, mussel and oysters. Wheat is barley, rye, oats and pelts, either in grain or flour.



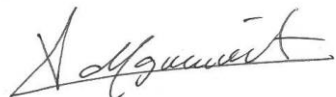


The severity of allergies varies by person and can range from minor irritation to anaphylaxis (a life-threatening emergency). While most allergies don't have a cure, treatments can help relieve allergy symptoms.

A food allergy can cause:

- Tingling in the mouth
- Swelling of the lips, tongue, face or throat
- Urticaria
- Anaphylaxis

3. DESIGNATION OF RESPONSIBILITIES

number	Area	Function	CELULAR TELEPHONE	Company
Sandra Castillo Cervantes	Quality Management	responsibl e	4433902495	
Cleotilde Sotomayor Arroyo	Production and Quality Supervisor	Validation	4431042226	
Margarita RuanThe Chavez	Production Management	Verificatio n	4432278397	

4. RISK ANALYSIS

A Failure Mode and Effect (AMEF) Analysis is performed and a "Priority Risk Number" is obtained also known as:

$$\text{NPR} = \text{Probability} \times \text{Severity} \times \text{Detection}$$

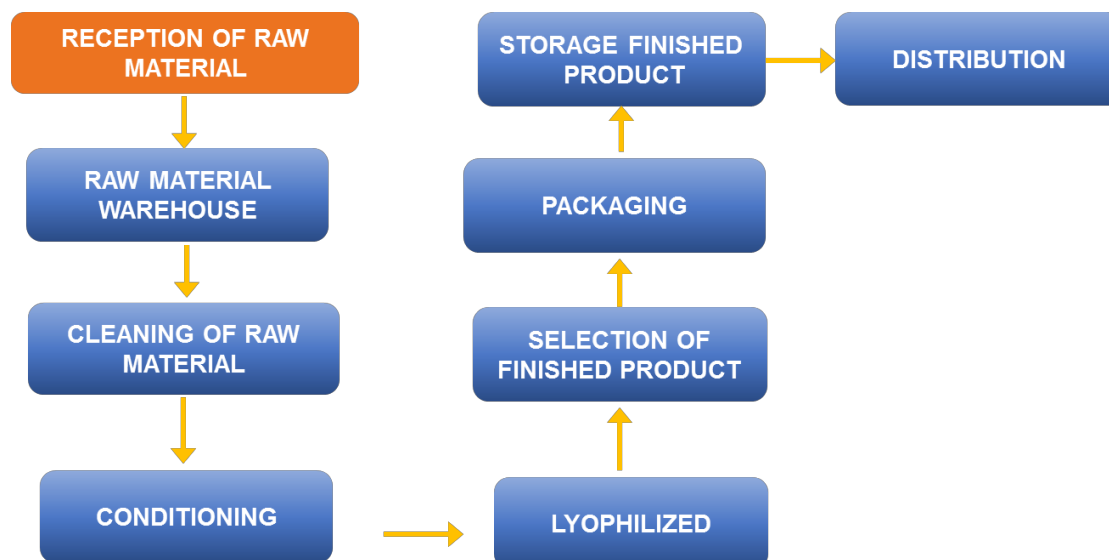
Severity: This is the estimate of the severity of the effect of the client failure mode.

Occurrence: is the probability that a specific cause will result in a failure mode.

Detection: is a value to classify the probability of finding the fault before the part reaches the customer



a) Flowchart



b) risk variables

Stage	Potential risk	Risk effect
MP Reception	Receive a raw material that is not properly identified and is used as a non-allergen product	Cross-pollution
MP Warehouse	Store a raw material in an unsuitable space.	Cross-pollution
Cleaning buckets and MP bags	No risk	Na
Conditioning (mixed)	Contamination of inert surfaces. Mixer and utensils.	Cross-pollution
Lyophilized	Contamination of inert surfaces. Lyophilizate chamber, trays.	Cross-pollution
Selection of pt	Contamination of inert surfaces. Tables and utensils	Cross-pollution
Packaging	No risk	Na
Pt storage	Store a finished product that is not properly identified and is used as a non-allergen product	Cross-pollution
Distribution	Mislabeled	Consumption.

c) Occurrence and Severity

Stage	Occurrence	Quantitative	Severity	Quantitative
MP Reception	Low: few faults	2	Low	1
MP Warehouse	Low: few faults	2	Low	1
Conditioning (mixed)	Moderate: Occasional failures	5	Media	3
Lyophilized	Moderate: Occasional failures	5	High average	4
Selection of pt	Moderate: Occasional failures	5	Media	3
Pt storage	Low: few faults	2	Low	1
Distribution	Low: few faults	2	Low	1



Qualification	
Quantitative	Probability
1	Remote: Improbable failure
2	Low: Few faults
3	
4	Moderate: Occasional failures
5	
6	
7	High: Frequent failures
8	
9	Very high: Persistent failures
10	

d) Detection

Stage	CONTROL	TYPES OF INSPECTION		Detection
		Visual inspection	Measurement	
MP Reception	Low: few faults	X		1
MP Warehouse	Low: few faults	X		1
Conditioning (mixed)	Moderate: Occasional failures	X		1
Lyophilized	Moderate: Occasional failures	X	X	1
Selection of pt	Moderate: Occasional failures	X		1
Pt storage	Low: few faults	X		1
Distribution	Low: few faults	X		1

Evaluation

Stage	Occurrence	Severity	Detection	NPR	SOD	SD	Priority FOR CONTROL
MP Reception	2	1	1	2	121	11	3
MP Warehouse	2	1	1	2	121	11	3
Conditioning (mixed)	5	3	1	15	351	13	2
Lyophilized	5	4	1	20	451	14	1
Selection of pt	5	3	1	15	351	13	2
Pt storage	2	1	1	2	121	11	3
Distribution	2	1	1	2	121	11	3

5. CONTROL OF ALLERGEN PRODUCTS IN SIOSI

The products that are handled in SIOSI are the following for them are available with Allergen Control:



- GUACAMOLE
- AVOCADO
- COCONUT
- COCONUT+ BANANA
- COCONUT + MANGO
- COCONUT + VANILLA

Within the products that are handled in SI OR IF Food, Coconut is the one that causes food allergy. The following foods are considered "nuts" according to the U.S. Food and Drug Administration (FDA) Guide Document, Center for Food Safety and Applied Nutrition (CFSAN), as well as the U.S. Food and Drug Administration Food Inspectorate U.S. Department of Agriculture (USDA).

COMMON NAME OR USUAL	SCIENTIFIC NAME
Almond	Prunus dulcis (Rosaceae)
Hayuco	Fagus spp. (Fagaceae)
Brazil nut	Bertholletia excelsa (Lecythidaceae)
White nut	Juglans cinerea (Juglandaceae)
Cashew	Western Anacardium (Anacardiaceae)
Chestnut (Chinese, American, European, Seguin)	Castanea spp. (Fagaceae)
Chinquapin nut	Castanea pumila (Fagaceae)
Coco	Cocos nucifera L. (Arecaceae (alt. Palmae))
Hazelnut	Corylus spp. (Betulaceae)
Ginkgo nut	Ginkgo biloba L. (Ginkgoaceae)
Hickory	Carya spp. (Juglandaceae)
Litchi nut	Litchi chinensis Sonn. (Sapindaceae)
Macadamia nut	Macadamia spp. (Proteaceae)
Pacana	Carya illinoensis (Juglandaceae)
Pinus spp. (Pineaceae)	
Pistachio	Pistacia real L. (Anacardiaceae)
Shea nut	
Nut (English, Persian, Black, Japanese, California)	Juglans spp. (Juglandaceae)

a) Reception

- When the product arrives at the plant arrives in 20-litre buckets it is checked that the labels of the raw materials that enter contain the appropriate information.

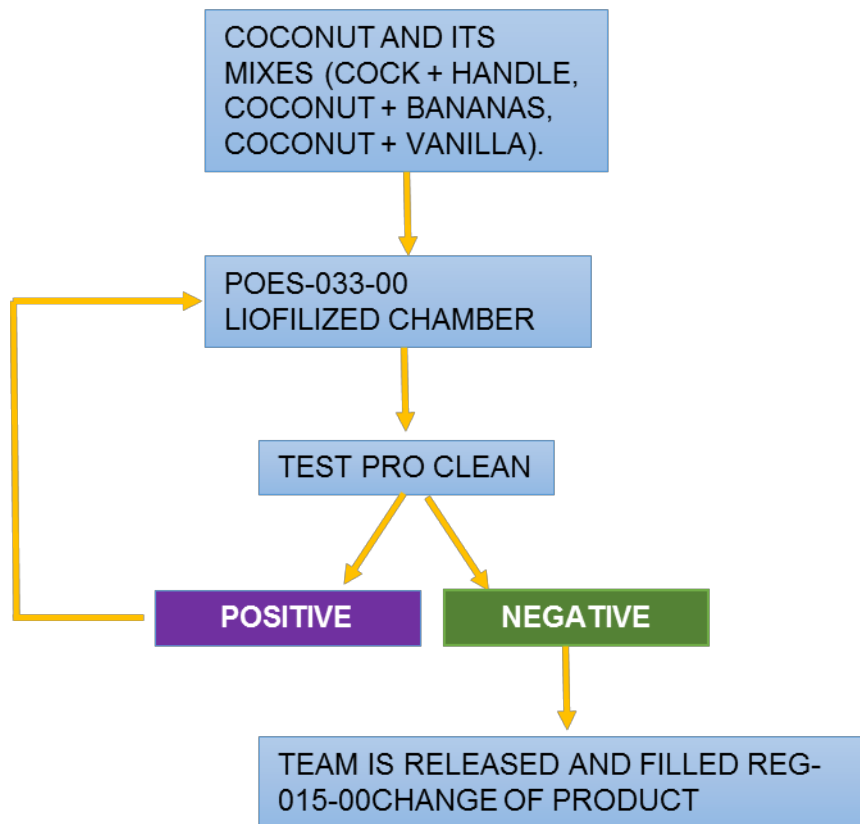


- Labeling according to MP specification for each product as appropriate ESP-004-00 COCO CREAM, to ensure full identification.
- Any damaged allergenic product container is handled appropriately to minimize cross-contamination during reception.

b) Storage

- Allergenic ingredients or products are stored separately to prevent cross-contamination. Utilizing clean, closed containers.
- Separate storage areas are available for ingredients or products to range and not allergens.
- The raw material and the finished product are placed in the designated place for a lérgeños and, where appropriate, can be identified with a Purple cone.

c) Determination of allergens in freeze-dried process.



1. Flowchart decision making in equipment washing.



In the context of food allergens, "cross contact" occurs when a residue or remnant of a food allergen is incorporated into another food that was not intended to contain it, which is why after producing coconut or some of the mixtures Coconut-vanilla, coconut-mango or coconut-banana, a cleaning is performed according to the POES-033-00 CAMERA OF LIOFILIZED ALEGRIA to ensure that any trace is removed.

At the end of the cleaning to be able to release the equipment the PRO-CLEAN test is performed. It is determined with the help of the aller-snap consists of the following:

- PRO-CLEAN (Aller-snap) is a quick test for protein residue detection, ready to use, PRO-CLEAN, change from green to violet color if proteins present in the sample are found.
- The color change will be faster and darker the more protein is accumulated in the sample.
- This test depends on time and temperature, so it is important to let the device reach room temperature (15-25°C).
- NOTE: This test is designed to detect invisible amounts or traces of product residue. When sampling it is important not to overload the swab with too much sample, as it may inhibit the reaction.
- The REG-015-00 PRODUCT CHANGE records whether the computer is released or rejected. In the event that cleaning is rejected, cleanup is re-implemented and re-verified, this is done as many times as necessary.
- Purple utensils are used to implement this cleaning to differentiate them from those used when handling non-allergen products to ensure proper cleaning and no cross-contamination.

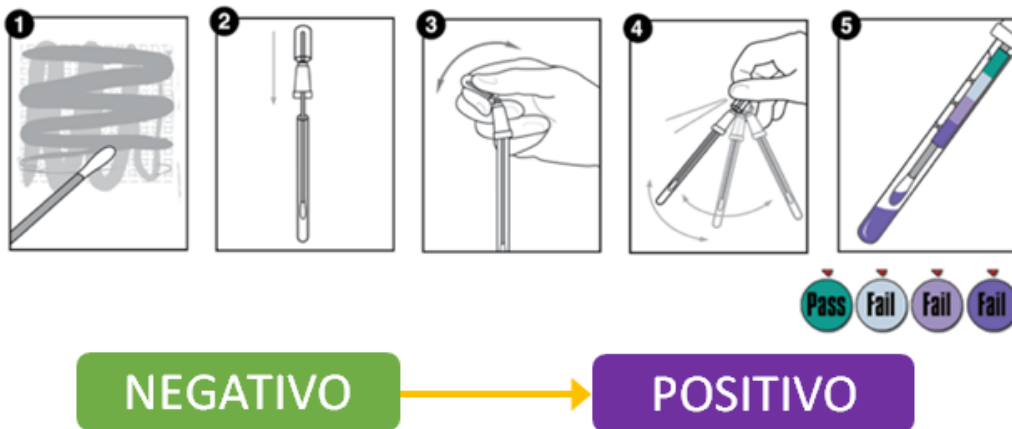
PROCEDIMIENTO PRO-CLEAN (Aller-snap)

1. Do not touch the swab on the bottom of the device as it may interfere with the sample result.
2. Removing the swab this comes moistened, scraping the surface to be analyzed in a standard area of 10x10 cm of interest for a flat surface-



3. After scraping the swab in the desired area to be analyzed, the swab is placed back into the tube.
4. To activate the device, hold the tube tightly and use your thumb and forefinger to break the valve, bending your head back and forth.
5. Gently moisten the swab in the liquid by shaking for 5 -10 seconds.
6. We wait 10 minutes, changing color from green to violet normally when there is presence changes in 60 seconds.

ALLER-Snap Instructions



7. Fig. Physical performance of results

6. Training

- Staff are trained on food allergens and the consequences of ingestion in sensitive people.
- Awareness-raising and training of staff is essential for the implementation of good manufacturing practices, especially to avoid the risk of cross-contamination. REG-002-01 MEETING ASSISTANCE LIST.

Produced by:	Validated by:	Verified by:
Production Manager	Quality Supervisor	Responsible Safety System



Annexes

REG-015-00 PRODUCT CHANGE

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ESTE DOCUMENTO ES PROPIEDAD DE SILOS ALIMENTOS, S.A. DE C.V. NO PODRÁ SER REPRODUCIDO O PUBLICADO FUERA DE LA ORGANIZACIÓN SIN PREVIO PERMISO POR ESCRITO POR PARTE DE LA DIRECCIÓN GENERAL.



REG-002-01 MEETING ASSISTANCE LIST.

Código	REG-002-01
Nombre	LISTA DE ASISTENCIA A REUNIONES
Fecha de emisión	21 de octubre del 2013
Fecha de modificación	28 de octubre de 2018
Objetivo	Llevar un registro de asistencia a reuniones de la empresa
Responsable	Responsable del sistema de Inocuidad.

MOTIVO DE LA REUNIÓN	
FECHA Y DURACIÓN	
PERSONA QUE IMPARTIÓ	

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